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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,977	04/14/2004	Arthur D. Ballard	60311-USA	7542

Paul A. Fair
Patent Administration
FMC Corporation
1735 Market Street
Philadelphia, PA 19103

7590 02/14/2008

EXAMINER

SILVERMAN, ERIC E

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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02/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/824,977

Applicant(s)

BALLARD ET AL.

Examiner

ERIC E. SILVERMAN

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 16, 17 and 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 11-14-05, 11-8-04, 9-23-04, 8-15-05, 7-26-04, 1-9-06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicants' election of Group I, claims 1 – 15, 18, 19, and 22 with traverse is noted. Applicants' traverse on the grounds that Groups I, III, V, and VI may be searched without undue burden, because they are were classified in the same class/subclass. Applicants' also argue that Groups II and IV may also be searched without undue burden.

In response, it is first noted that because Applicants have not specifically argued why the restriction of Groups I, III, V, VI from Groups II and IV, the restriction with respect to those sets of Groups is being deemed as **without traverse**.

With respect to Groups I, III, V, and VI, Applicants' argument is partially persuasive, and Group V, claims 22 and 23, is **rejoined**. With respect to the remaining restriction requirement, search of Groups III and VI would be burdensome because those Groups have a different active film-former (polymanan gum) than that of the elected Group (low viscosity guar gum). The argument that Groups II and IV were not properly restricted from each other is moot, because Applicant has not elected either of those Groups, nor does Applicant argue that either of those Groups was improperly restricted from the elected Group.

Applicants' election of the species of films without plasticizers is also acknowledged. Applicant avers that claims 1 – 15, 18, and 19 read on the elected species. Rejoined claims 22 and 23 read on the non-elected species of films without plasticizers (claim 23 recites a composition consisting of guar gum, a bulking agent, an

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active substance and water, which does not allow for addition of a plasticizer), these claims will be withdrawn as being drawn to a non-elected species.

As such, the remainder of the restriction requirement is still deemed proper, and is made **FINAL**.

/M. G. H./

Supervisory Patent Examiner, Art Unit 1618

Claims 1 – 27 are pending. Claims 16, 17, and 20 – 27 are withdrawn as reading on a non-elected invention or species. Claims 1 – 15, 18 and 19 are treated on the merits in this action.

Information Disclosure Statement

Various foreign patent documents on the Information Disclosure Statements received 11/14/2005 and 7/26/2004 have not been considered because Applicants have provided neither an English translation nor a statement of relevance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 3 – 8, 10, 12 – 15, 18, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 17 of copending Application No. 10/824,956. Although the conflicting claims are not identical, they are not patentably distinct from each other because while instant claim 1 does not require a second film former, a bulking agent or a pH controlling agent, while copending claim 1 does require these. Copending claim 1 is therefore a species of instant generic claim 1, rendering the instant claim obvious. The active of instant claims is not required by copending claims, but the "second film formers" of copending claim 2 include such materials as pectin or starch, which read on the food, salivary stimulant, or nutraceutical actives of instant claim 2. So copending claims do suggest the active of instant claims. The remaining copending claims have essentially identical limitations to the remaining instant claims, thereby rendering instant claims obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 15, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "low viscosity guar gum". It is not clear what viscosities are "low", according to the claim. "Low" is a relative term, and no basis for comparison is given.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 10 recites the broad recitation starch derivative, and the claim also recites starch hydrozylate which is the narrower statement of the range/limitation. Claim 11 includes the same recitation, and also includes the broad recitation "alginates" along with "propylene glycol alginate" which is a narrower statement of the range or limitation.

Claim 9 requires that guar gum be the only film former present in the gel film. However, certain materials, such as starch, starch derivatives, and starch hydrozylates, are both film formers and bulking agents according to instant claims (see instant claim 11 as an example). It is not clear if such materials may be included as bulking agents, or if they are excluded because they may also serve as film formers.

Claim 10 and 11 recite "starch derivative". Absent a limiting definition in the specification, it is unclear what materials are "derivative[s]" of starch, as claimed.

Claim 11 requires specific plasticizers, second film formers, and bulking agents. However, some of the bulking agents are also second film formers, for example, starch and starch hydrozylates. If, for example, starch is present, it is not clear if starch serves as both the bulking agent and second film former, or if an additional bulking agent or second film former are also required. This confusion also exists for the plasticizers, because some of the plasticizers (fructose and polydextrose, for example) are also active agents because they are either "salivary stimulant agent[s]", sweeteners, or nutraceuticals, according to claim 2 (claim 2 listing various types of active agents).

Claims 12 – 16, 18 and 19 recite a "break force strength" measured in grams. Grams are measurements of mass, not of force. Force is measured in units such as pounds (lbs) or Newtons (N). For the purpose of compact prosecution, this limitation is being understood to be an inherent property of the delivery system of claim 1, because all of these claims depend on claim 1.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 3, 5 – 15, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,177,065 to Silvetti, Sr. et al. ("Silvetti").

Silvetti teaches a composition comprising fructose, starch hydrolysate and a second film forming agent other than starch hydrolysate (claim 1). The second film forming agent may be guar gum (claim 2), and is present in about 25% to 50% of the overall composition (claim 4). The composition is applied as a film in at least one example (col. 11, lines 14 – 15).

Instant claim 1 requires a film comprising a film forming amount of a low viscosity guar gum and an active substance. Absent a specific definition of which viscosities are low, the guar gum of the art is understood to meet this limitation. According instant claim 2, sweeteners are active substances; the fructose of Silvetti is a sweetener and thus meets this limitation.

Instant claims 3 requires that the guar gum be present in greater than 0.25%; this limitation is met by the art's teaching of 25% - 50% by weight of the second film forming agent (guar gum) in patented claim 4.

Instant claims 5 – 9 require that the guar gum be present as at least a given per cent of the total film formers in the film, and instant claim 9 requires that the guar gum be the only film former. Affording these claims their broadest reasonable interpretation, the starch hydrolysate of the art is considered *not* to be a film former for the rejection of instant claims 5 – 9. This interpretation is reasonable because according to instant claim 11, starch hydrolysate is a bulking agent.

Instant claims 10 and 11, which require the use of particular second film formers, particular plasticizers, and particular bulking agents. As these claims are interpreted, fructose is both the active agent (as discussed above) and the plasticizer, and the starch hydrolysates are both the bulking agent and the second film former. This interpretation is reasonable because the claims list sweeteners as actives and fructose as a plasticizer, and do not preclude the active from also being the plasticizer; further, the claims list starch hydrolysates as being both a film former and bulking agent and do not preclude the film former and bulking agent from both being starch hydrolysates.

Claims 12 – 15, 18, and 19 recite a property of the delivery system of claim 1, namely the break force strength. Because a composition is not separable from its properties, the recited break force strength is deemed to be an inherent property of the prior art composition which is the same composition recited in claim 1.

Claims 1, 2, 12 – 15, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 62-186754, of record (see IDS filed 7/26/2004; the provided translation is relied upon).

The JP'754 reference teaches a composition obtained by blending a polysaccharide and a second substance. The polysaccharide may be guar gum as per instant claim 1 ('754 claim 1), and the other substance is a sweetener, as per instant claim 2, such as a sugar alcohol, monosaccharide, or disaccharide ('754 claim 1). The composition is present in the form of an edible film (Section 3. Detailed description of the invention). Instant claims 12 – 15, 18, and 19 recite a property of the delivery system of claim 1, namely the break force strength. Because a composition is not

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separable from its properties, the recited break force strength is deemed to be an inherent property of the prior art composition which is the same composition recited in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/92400, of record (See IDS filed 7/26/2004).

The WO reference discloses a film forming composition having 25-75% starch material, 25 - 75% plasticizer and 0 - 15% gum or synthetic polymer (claim 8). The starch material may be modified starch (claim 1 or a starch derivative (claim 14). In embodiments where the gum or synthetic polymer is required to be present, it may be

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guar gum (claim 9). The plasticizer is a substances such as glycerol, sorbitol, fructose, sucrose, etc. (claim 20).

The WO reference does not require a gum, such as the guar gum, nor the plasticizers.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include the guar gum, because this is a claimed embodiment of the invention. Obviousness stems from the express suggestion in the art. Because the inclusion of guar gum was expressly suggested by the inventor, the artisan would enjoy a reasonable expectation of success.

Note that with respect to instant claims 1 and 2, the "active agent" may be a sweetener; most of the suggested plasticizers of WO claim 20, such as fructose and sucrose, are sweeteners. Therefore these materials are also the "active agents" of instant claims. Claim 1 requires "low viscosity" guar gum, but does not define what viscosities are "low"; the guar gum of WO is understood to meet this limitation.

With respect to instant claims 3 and 4, the guar gum, when present in the WO composition, is present in up to 15%, substantially overlapping with the claimed ranges of guar gum (greater than 0.25% and between 0.25% and 25%, respectively), thus rendering these claim limitations obvious.

With respect to instant claims 5 – 9, which require that the guar gum be more than the specified amounts of the total weight of film formers (in claim 9, the guar gum is the only film former), note that the other recited ingredients are a modified starch and a plasticizer. The plasticizer is not a film former, and a starch derivative may be

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interpreted as being a bulking agent and not a film former, according to instant claim 11, which defined starch derivatives as a bulking agent. So in this interpretation of the claims, guar gum is the only film former.

The inclusion of starch derivatives or starch compounds in WO reads on the film formers of instant claim 10.

With regard to instant claim 11, the starch derivative of WO claim 14 meets the requirement for the film former and bulking agent, and the plasticizers of WO claim 20 include the plasticizers of the instant claim. The instant claims do not preclude the plasticizer from also being the active agent, nor do they preclude the bulking agent from also being the second film former.

With regard to instant claims 12 – 15, 18 and 19, these claims recite a break force strength of the delivery system of claim 1. This strength is an inherent property of the composition, and the suggested composition would also have this property.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. JP5416352 (Dec. 1979) is cited for a teaching of compositions containing active agent oils, gums such as guar gum, and other ingredients. The JP'352 composition is an emulsion, not a film.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is

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(571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman, PhD/
Examiner, Art Unit 1618